DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 14 -16, 19, 20 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) [*and Kasprzyk (US 5,114,423) which is incorporated by reference at C6:L52-56*] in view of Stack (US 6,264,683).

3. Lau discloses a stent delivery system (see entire reference in particular C6:L35-C7:L2 and note US 5114423 to Kasprzyk incorporated by reference) comprising: [see Fig. 1 of Kasprzyk] an inner tube (14) comprising a proximal end, a distal end, and a lumen (15) extending therebetween, the inner tube being disposed within an outer tube (11) with an annular space (32) disposed therebetween, the distal end of the inner tube further comprising a distal tip (for example at location 31 or 15) a heating element (24) positioned around the inner tube proximal to the distal tip, the outer tube comprising a proximal end (13) and a distal end, the distal end of the outer tube being disposed proximally to the distal tip of the inner tube and defining a distal end diameter (see Fig. 1), the distal end of the outer tube being connected to a balloon (23) which extends between the distal end of the outer tube and the distal tip of the inner tube, the balloon overlying the heating element (for example portion 30), wherein the annular space is not

in fluid communication with the lumen of the inner tube and an exterior of the balloon, and [see Fig. 1-3 of Lau] an expandable stent (10) positioned around the balloon and disposed between the distal end of the outer tube and the distal tip. Regarding claim 4: the balloon is also connected to the distal tip of the inner tube (see Kasprzyk, Figure 1). Lau further discloses the steps of inserting the stent delivery system with the stent in the unexpanded form, into the vasculature system and to a desired position, and heating the stent to expand the stent and causing it to adhere to the vasculature system at the desired position (CC4:L53-C5:L6 and C6:L44-56); deflating the balloon, and withdrawing the inner and outer tubes and balloon from the vasculature system (it is inherent that the balloon would be deflated (C4:L53-C5::L25) in order for the catheter to be withdrawn from the vasculature after the stent is delivered to its desired site). Regarding claim 15: during the heating of the stent, the balloon is heated and partially inflated (C6:L41-52). Regarding claim 16, during the inserting step, the balloon and stent are cooled (relative to the warm temperature applied to the stent during deployment at the site of the stenosis). Regarding claim 19: the heating is performed using a heating element. Regarding claim 27: Lau discloses supplying current to the heating element to expand the stent and causing it to adhere to the vasculature at the desired position (Lau C6:L41-52 and Kasprzyk C5:L(45-57).

4. Lau does not explicitly disclose that the edge diameter of the tapered distal tip of the inner tube and the distal end diameter of the outer tube are equal to or greater than a maximum outer diameter of the stent in an unexpanded form. However, Stack discloses a stent delivery device with an inner tube having a tapered distal tip (20) with

a proximal edge diameter and an outer tube defining a distal end diameter, wherein both diameters are equal to or greater than a maximum outer diameter of the stent in an unexpanded form (Figs. 1-4) in order to prevent slippage of the stent and prevent the stent from contacting the vessel wall during delivery (C1:L42-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate retainers on the deliver device of Lashinski to achieve the same advantages.

5. With respect to claim 20, Lau/Kasprzyk does not disclose the heating element is a coil with a power line and a return line encased in a layer of insulating material (in reference to the embodiment of Figure 1). However, Kasprzyk discloses another embodiment (Figure 4) that incorporates the use of a coil heating element (50, 51) for supplying heat to the immediate area surrounding a balloon (C6:L16-22). The heating element is connected to a power supply (33) via a power line and a return line which are insulated (C4:L52-C5:L25). It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute a heating element that is a coil in place of the conductive coaxial cable. The substitution of one known element for another would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution would have yielded predictable results, namely, a manner of heating the stent for expansion.

6. Claims 1, 3-9, 12, 13, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 6,264,683) and further in view of Lashinski (6,579,305).

7. Lau discloses the invention substantially as claimed as stated above. Lau discloses a stent that is transitioned by a change in temperature but the stent is plastic rather than shape memory. Lau discloses a stent made of shape memory, but the shape memory stent is transitioned by a change in stress rather than a change in temperature (C6:L35-C7:L2). Lashinski discloses wherein the stent is formed of a stent material having a shape memory transition temperature lower than an elevated temperature produced by the heating element so that the stent expands in response to the heating provided by the heating element (C1:L43-62; C4:L43-54). Doing so provides more control over expansion and eliminates the need for an outer sheath thereby reducing the overall profile and improving the ability to navigate tortuous vessels (C2:L33-61). Lashinski further discloses: regarding claims 6 and 25: the stent comprises nitinol (C1:L45). Regarding claim 7 and 26: the stent is a self-expanding stent (C4:L51 where the stent is shape memory nitinol and expanded by influence of heat). In light of the teachings of Lau and Lashinski, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a heat transition stent in place of a stress induced transition stent to achieve the more expansion control and a reduced profile. Regarding claims 5 and 24: both Lau (C4:L33-36) and Lashinski (C4:L2) disclose the stent is crimped onto the balloon. Regarding claim 8, both Lau (4:L25-32) and Lashinski disclose the balloon is made of elastomeric material.

8. With respect to claims 3, 12 and 13, Lau/Kasprzyk does not disclose the heating element is a coil with a power line and a return line encased in a layer of insulating material (in reference to the embodiment of Figure 1). However, Kasprzyk discloses

another embodiment (Figure 4) that incorporates the use of a coil heating element (50, 51) for supplying heat to the immediate area surrounding a balloon (C6:L16-22). The heating element is connected to a power supply (33) via a power line and a return line which are insulated (C4:L52-C5:L25). It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute a heating element that is a coil in place of the conductive coaxial cable. The substitution of one known element for another would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution would have yielded predictable results, namely, a manner of heating the stent for expansion.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 6,264,683) and Lashinski (6,579,305) and further in view of Fischell (US 5,976,153).

10. Modified Lau discloses the invention substantially as claimed as stated above but does not disclose a radiopaque marker. However, Fischell teaches a distal radiopaque marker (13d) disposed immediately proximal to the distal tip and a proximal radiopaque marker (13p) which is disposed immediately distal to the distal end of the outer tube (for example as seen in configuration of Fig. 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate radiopaque markers in order to better track the delivery device and more accurately place the stent.

11. Claim 17, 18, 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 2,264,683) as applied to claims 14, 16 and 27 above, and further in view of Rabkin (US 6,676,692)

12. Modified Lau discloses the invention substantially as claimed as stated above but does not disclose the use of a using warm saline solution for heating the stent. However, Rabkin discloses that it is well known in the art to use a warm saline solution delivered into the balloon in order to achieve the transition temperature of the stent for expansion. It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute the use of a warm saline solution in place of a conductive cable or coil in order to effect the transition of the stent.

The substitution of one known element for another would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution would have yielded predictable results, namely, a way of achieving the transition temperature of the stent for expansion. KSR, 550 U.S. at, 82 USPQ2d at 1396.

13. Modified Lau discloses the invention substantially as claimed as stated above but does not disclose the use of cool saline solution to cool the stent and balloon during delivery. However Rabkin discloses that it is well known in the art to use a cooling fluid during delivery to ensure that the stent does not expand prematurely (C18:L13-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this same feature to achieve the same advantage.

14. Claims 21 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 6,264,683) as applied to claims 19 and 27 above and further in view of Healy (US 6607553).

15. Modified Lau does not further disclose a thermocouple located on the distal end of the inner tube for monitoring the temperature. However Healy discloses the use of a thermocouple for monitoring that the temperature of the stent is high enough to transition the stent without being too high too damage the tissue (C8:L52-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a thermocouple for the same advantage. Regarding the location of the thermocouple it would have been obvious to one having ordinary skill in the art at the time the invention was made relocate the thermocouple to location that provides the most efficient feedback for its use since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Response to Arguments

16. Applicant's arguments filed 07/11/11 have been fully considered but they are not persuasive. Applicant notes that examiner has used an uncited reference, Kasprzyk (US 5,114,423). Examiner would like to point out that the Kasprzyk reference was fully incorporated into the cited reference Lau (US 5,421,955) and thus all of the contents of the Kasprzyk reference are considered an extension of the full disclosure of Lau. Examiner clearly noted that Kasprzyk was incorporated by reference in the first like of

the body of the rejection and clearly identifies when the reference is relied on throughout the rejection.

17. Applicant argues that Lau does not disclose the edge diameter and distal end diameter are equal to or greater than a maximum outer diameter of the stent in the unexpanded form. Examiner concedes this fact (see paragraph 4 above) and remedies the deficiencies through the teachings of Stack. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

18. Applicant attacks Kasprzyk for not having a distal tip in which the proximal edge diameter is equal to or greater than the diameter of the stent in the unexpanded form. Again, Kasprzyk is not relied on for disclosing the specific structure of the distal tip. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In order to show analogy, examiner points to reference 31 (for example) with respect to the distal tip to show the location of the distal tip of the catheter. Examiner asserts that all balloon catheters have an area that can be considered a distal tip as there is no specific structure associated with the term "tip". Examiner makes no assertion that Kasprzyk discloses a proximal edge having a diameter larger than the stent.

19. Applicant argues that Kasprzyk does not disclose "an annular space between the inner tube and the outer tube" since a significant fraction of the space between the two elements is occupied by coaxial cable 24. However the face that there is additional structure between the two tubes does not take away from the fact that there is in fact an annular space between the two tubes.

20. Applicant argues that it is not necessarily inherent that the balloon would be deflated and removed after the stent is delivered. Applicant notes that there is nothing in Lau that indicates that the balloon must necessarily frictionally engage the stent and further notes the use of the sheath to hold the stent in place. However, it appears that applicant is only referring to the deflated delivery configuration and does not take into account that once the balloon is expanded to deploy the stent it necessarily comes in contact with the stent. Further, Lau notes that one of the manners in which the stent is secured to the balloon is by slightly inflating the balloon (C4:L54-58). Thus, the balloon would necessarily need to be deflated in order to release the stent and remove the catheter from the patient.

21. Applicant argues that Stack does not disclose an inner tube and an outer tube but rather a tube with two lumens. However, examiner asserts that it is not necessary for Stack to actually disclose two tubes since it is the teaching of the stent bumpers for which Stack is relied on. Examiner refers to Stack having an inner tube and an outer tube for the purpose of showing analogy and how the stent bumpers would readily apply to the Lau reference. Even though the structure is not identical, there is a similarity between inner and outer tubes of Stack with respect to the inner and outer tubes of

Lau/Kasprzyk that would allow one of ordinary skill the art to readily determine how to apply the teachings of Stack to the device of Lau/Kasprzyk. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571) 272-7134. The examiner can normally be reached on Monday – Friday from 9:00am to 5:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, TOM HUGHES, at (571) 272-4357***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

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/Elizabeth Houston/
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09/23/11